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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,149

Applicant(s)

HINCHLIFFE, PETER W.J.

Examiner

Cris L. Rodriguez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12 and 15-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12 and 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-8, and 10-25 in Paper No. 9 is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed July 2, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "rotatable thrombectomy wire"; "the catheter having an asymmetrical exterior" as set forth in claim 5; the first balloon being positioned proximally of the other balloon as set forth in claims 18, 24 and 25 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:
 - The specification on page 6 lines 15-19 is completely confusing. The specification refers to a rotatable thrombectomy device 22 (fig. 1) when in figure 2 it is shown as

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part of the catheter. Figures 1-5 show a catheter, and nowhere show a rotatable thrombectomy device. Moreover, the description to the wire as having a J-shaped tip seem confusing since figure 2 shows that it is part of the catheter 12;

- The specification does not have a description for figures 4 and 5.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 16, there is no positive recitation for “the thrombectomy device”.
- Claim 18 is indefinite and confusing because it is not clear the scope of the claim since claim 1 set forth that the first balloon is positioned proximate of a first catheter end and the second balloon is inboard of the first balloon. Claim 18 set forth the opposite; therefore the scope of the claim is unclear.
- Claim 24 is vague because it is not clear what applicant intends to encompass with “the first balloon is in the form of an angioplasty balloon”.
- Claims 19-25 are indefinite because the scope of the claimed subject matter is unclear due to inconsistencies between the language of the claims preamble and certain portions of the body of the claims. The preamble of claim 11 sets forth the subcombination of the catheter. However, claim 19 recites the rotatable

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thrombectomy wire in structural relationship to the catheter. This sets forth a positive relationship between catheter and rotatable thrombectomy wire, and thus the claim appears to claim the combination of catheter and rotatable thrombectomy wire.

Applicant needs to amend the language of the claim to be consistent either as the combination or subcombination claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims are 1, 2, 4-8, and 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Schulze (US 6,056,721).

Schulze discloses an angioplasty catheter (figs. 2-8) with at least three axially non-communicating passages, a guidewire lumen 28d, a first balloon 150 (fig. 8) and a second balloon 146.

9. Claim 3 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schulze.

Schulze discloses that the second balloon can be made of a low compliance angioplasty balloon as well known for those skilled in the art. (Col. 7 lines 44-48). Schulze is moot to the balloon being made specifically of PET. However, since PET it is a well-known

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low compliance material used to make angioplasty balloons, it would inherently be selected from the variety of the well-known low compliance materials for balloons, which includes PET. Otherwise, the selection of a well known material, such as PET as a low compliance material for an angioplasty balloon, has been rendered as an obvious design choice, since the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shulze in view of Zacca (US 5,766,192).

Shulze discloses the invention substantially as claimed. However, Shulze fails to disclose a guidewire that rotates to perform thrombectomy.

Zacca teaches a combination of an angioplasty catheter (fig 12) and an atherectomy device with a rotatable tip 116 (col. 5 lines 63-col. 6 line 19, and col. 18 line 51-col. 19 line 9)). Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute Zacca's angioplasty catheter with Shulze's angioplasty catheter. Doing so would have guided the angioplasty through the vasculature and performed thrombectomy.

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Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kokish et al, Nash et al, Forman et al, Bacher et al, Lemelson et al, Pierpont, Andrews, Carbo et al, Bodden, Nelson, Jr., and Zadno-Azizi..


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

December 13, 2002


Cris L. Rodriguez
Examiner
Art Unit 3763


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